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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/668,266	09/22/2000	Keith E. Robison	35800/204489	9505

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EXAMINER

SISSON, BRADLEY L

ART UNIT

PAPER NUMBER

1634

DATE MAILED: 05/09/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/668,266

Applicant(s)

ROBISON ET AL.

Examiner

Bradley L. Sisson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 March 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 19,21,29,30,32-35 and 44-56 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 19,21,29,30,32-35 and 44-56 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114 was filed in this application after appeal to the Board of Patent Appeals and Interferences, but prior to a decision on the appeal. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 05 March 2002 has been entered.

Location of Application

2. The location of the subject application has changed. The subject application is now located in Group 1630, Art Unit 1634, and has been assigned to Primary Examiner Bradley L. Sisson.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 19, 21, 29, 30, 32-35, and 44-56 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the

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application was filed, had possession of the claimed invention. Claims 19, 21, 29, 32-35, and 44-56 are all drawn to an "isolated polypeptide." The claims, however, do not necessarily adequately describe the polypeptide being claimed. Using claims 19, 21, and 29 as examples, it is seen in the case of claim 19 that at least one embodiment defines the isolated polypeptide not in terms of what it is but where a cDNA construct may be located. While defining the polypeptide in terms of a deposited cDNA sequence may go to serve enablement for the production of the polypeptide, and possibly the possession of the polypeptide, it does not satisfy the written description requirement as one is not able to readily determine if a given protein is or is not different from what is being claimed. In support of this position, attention is directed to the decision of *University of California v. Eli Lilly and Co.* (CA FC, July 1997) 43 USPQ2d 1398 wherein is stated that an adequate written description of genetic material "requires a precise definition, such as by structure, formula, chemical name, or physical properties." *Id.* at 1404 (quoting *Fiers*, 25 USPQ2d at 1606). While the instant claims are not drawn to genetic material per se, they do attempt to define the claimed polypeptide in terms of it being encoded by genetic material, which has not been adequately described.

5. In the case of claim 21, it is noted that the polypeptide "further comprises heterologous amino acid sequences." Again, the claim does not define what is present even in the first instance; much less describe what else is present. To describe the polypeptide in terms of it being comprised of "heterologous sequences," when the very underlying amino acid sequence is less than clearly defined, does not add to the clarity, but detracts therefrom.

6. Claim 29 seeks to define the polypeptide not in terms of what it is, *i.e.* "structure, formula, chemical name, or physical properties," but by defining how a nucleic acid that encodes it would have some percent identity. Even to define a nucleic acid in terms of its ability to encode a polypeptide is not an adequate written description of the nucleic acid as such is to define the nucleic acid in terms of how it is to function, not in terms of what it is. In the instant

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case, the specification does not reasonably suggest that applicant was in possession of the genus of nucleic acid sequences, or the deduced polypeptide sequences, at the time of filing. A review of the specification finds but two polypeptide sequences having been adequately described: SEQ ID NO:1 and SEQ ID NO:3. A review of the specification fails to find adequate support for possession or description of any other sequence.

7. In the case of claims 44 and 45, the claimed polypeptide can comprise additional amino acids residues without limit. And in the case of claims 55 and 56, the claims have been limited to segments of at least 50 amino acids from each of SEQ ID NO:1 and SEQ ID NO:3, and that there may be additional sequences present. While the specification has been found to adequately describe SEQ ID NO:1 and SEQ ID NO:3, the specification has not provided an adequate written description of just which regions of the defined polypeptide are required in order to preserve the requisite activity. Additionally, the specification has not been found to provide an adequate written description of what type and number of amino acid residues can be added to the polypeptide of SEQ ID NO:1 or 3, of fragments thereof, and the resultant polypeptide still be useful.

8. Claims 19, 21, 44-46, 53, and 54 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. As presently worded, the isolated polypeptide of claims 19, 21, 44-46, 53, and 54 is not required to have any specific enzymatic activity. Upon review of the disclosure, it is apparent that the invention lies in an isolated polypeptide that has phosphodiesterase activity; yet such activity is not required of the isolated polypeptide of these claims. The specification has not been found to teach a reproducible method of using an inactive form of the polypeptide, whether or not it has heterologous sequences.

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9. As see above, the specification has been failed to satisfy the written description requirement and fails to reasonably suggest that applicant was in possession of the invention at the time of filing. It is well settled that one cannot enable the use of an invention that they do not yet possess. As seen below, these claims have also been rejected under 35 USC 101 as not having patentable utility. It is well settled that one cannot enable the use of an invention that lacks patentable utility. Accordingly, and in the absence of evidence to the contrary, the specification has not enabled the isolated polypeptide of claims 19, 21, 29, 32-35, and 44-56.

Response to arguments

10. At pages 5-6 of the response received 20 November 2001 it is asserted that the claimed invention is adequately described as the claims have been defined in part by the activity of the isolated polypeptide- it is to act as a phosphodiesterase. This argument has been fully considered and has not been found persuasive as to indicate that a polypeptide is a certain type of enzyme is to specify how it is to function, not what it is. As set forth in *Lilly*, one can satisfy the written description of a chemical product if the description is one where it provides "a precise definition, such as by structure, formula, chemical name, or physical properties." It is noted with particularity that the Court did not hold that functional attributes could be used to satisfy this requirement. Accordingly, for applicant to attempt to satisfy the written description requirement by providing a definition couched in functional attributes is not considered sufficient to satisfy the written description requirements.

11. To define the polypeptide not in terms of its amino acid but in terms of an encoding nucleic acid sequence also does not adequately define the sequence of the polypeptide. The aspect of a given nucleic acid encoding a polypeptide speaks in terms of how it is to function, not

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in terms of what it is. Consequently, one knows not exactly what the claimed polypeptide sequence is. Similarly, to define the polypeptide in terms of not what it is but where one may find a deposited cDNA construct does not provide a description of what the claimed polypeptide is, but rather, suggests that the public may find starting materials that could be used in the production of the polypeptide.

12. At page 9 of the response argument is advanced that the Office has mischaracterized the invention in that claims are “directed to polypeptides having the amino acid sequences given SEQ ID NO:1, SEQ ID NO:3, or the amino acid sequence encoded by the cDNA insert of the plasmid deposited with ATCC as Patent Deposit No. PTA-1644. Applicants have demonstrated that these amino acid sequences share a high degree of sequence identity with phosphodiesterase as described above. Claims 29, 30, 32-34, and 47-56 specifically recite that the claimed variants and fragments have phosphodiesterase activity.”

13. The above argument has been fully considered and has not been found persuasive. While agreement is reached in that claims 29, 30, 55, and 56 do recite a limitation that the polypeptide exhibit phosphodiesterase activity, such is not necessarily required of the other claims. In fact, claims 19, 21, 32, 33, and 44-52 make no such requirement. In the case of claims 53 and 54, it is noted that of the three members of the group that the polypeptide can be selected from, two do not require this type of activity. As indicated above, while the claims are read in light of the specification, limitations found therein are not read into the claims. While a given polypeptide may have a particular or even a similar amino acid sequence, the sequence alone does not ensure a given activity. Given that the activity of a polypeptide, if it has any, is due to not only the amino acid sequence but also to the polypeptide acquiring a specific tertiary conformation that in

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turns allows it to act in a given manner. Accordingly, applicant is urged to again consider limiting the claims to those polypeptides that not only have a known amino acid sequence that is associated with phosphodiesterase activity, to also specify that the isolated polypeptide has such activity.

14. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

15. Claims 19, 21, 44-46, 53, and 54 are rejected under 35 U.S.C. 112, second paragraph, as failing to set forth the subject matter which applicant(s) regard as their invention. Evidence that claims 19, 21, 44-46, 53, and 54 fail(s) to correspond in scope with that which applicant(s) regard as the invention can be found in Paper No. 13 filed 20 November 2001. In that paper, applicant has stated "the claimed genus in the present application is defined in the specification by the functional properties (*i.e.*, phosphodiesterase activity) and the structural properties," and this statement indicates that the invention is different from what is defined in the claim(s) because the polypeptide of claims 19, 21, 44-46, 53, and 54 is not required to have any phosphodiesterase activity. It is noted with particularity that limitations found in the body of the specification are not read into the claims.

16. Claims 29, 30, 34, 35, 53, 54 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. As presently worded, the invention of claims 30, 35 and 54 recite the limitation that the polypeptide comprises "heterologous sequences." Given that the sequence of amino acids found in the underlying isolated polypeptide need not be that of the

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parent sequences, *i.e.*, SEQ ID NO: 1 or SEQ ID NO:3, it is less than clear just what constitutes a “heterologous sequence.” Claims 30, 35, and 54 depend from independent claims 29, 34, and 53. In view of an independent claim encompassing all limitations of its dependent claim, claims 29, 34, and 53 have been similarly rejected in this regard as they fail to resolve this issue.

Claim Rejections - 35 USC § 101

17. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title.

18. Claims 19, 21, 44-47, and 53-54 are rejected under 35 U.S.C. 101 because the claimed invention lacks patentable utility. As presently worded, the polypeptide of claims 19, 21, 44-47, and 53-54 is not required to have any specific enzymatic activity. Upon review of the specification, it is apparent that the only utility ascribed to the polypeptide is in that it needs to exhibit phosphodiesterase activity. Such activity is not required of the isolated polypeptide of the instant claims. In the case of claim 53 it is noted that at least three embodiments are provided, two of which are not required to exhibit any activity. Accordingly, claims 53 and 54 are considered to embody non-functional polypeptides, as do claims 19, 21, and 44-47.

Response to argument

19. At page 11 of the response applicant asserts that the rejection of claims under 35 USC 101 can be withdrawn as the claims are drawn to polypeptides that have been shown to have phosphodiesterase activity. Attention is also directed to claims 29, 30, 32-35, and 47-56 for specifically reciting that the isolated polypeptide has this enzymatic activity.

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Applicant's argument has been fully considered and has been found persuasive with regards to claims 29, 30, 32-35, 55, and 56. However, and as noted above, the isolated polypeptide of claims 19, 21, 44-47, and 53-54 is not so limited and accordingly, the rejection is maintained against previously pending claims and is applied anew against claims 44-47, 53, and 54.

Conclusion

20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradley L. Sisson whose telephone number is (703) 308-3978.

The examiner can normally be reached on 6:30 a.m. to 5 p.m., Monday through Thursday.

21. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached on (703) 308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

22. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



Bradley L. Sisson
Primary Examiner
Art Unit 1634

BLS
May 8, 2002